

K083898
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510(k) Summary

This 510(k) summary for SurgiMend is being submitted in accordance with the requirements of 21 CFR 807.92.

FEB -4 2009

Submitted by

TEI Biosciences Inc.
7 Elkins Street
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(617) 268-1616
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Contact Person

Kenneth James, Ph.D.
Vice President, Product Sciences and Regulatory Affairs

Date Prepared

July 31, 2007

Device Information

Proprietary name:	SurgiMend Collagen Matrix for Soft Tissue Reconstruction
Classification name:	Surgical Mesh
Device classification:	Class II

Device Description

SurgiMend is an acellular dermal tissue matrix derived from bovine dermis. The device is supplied sterile in a variety of sizes to be trimmed by the surgeon to meet the individual patient's needs.

Intended Use

SurgiMend is intended for implantation to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes.

SurgiMend is specifically indicated for:

- Plastic and reconstructive surgery
- Muscle flap reinforcement
- Hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias

Legally Marketed Devices to which Equivalence is Being Claimed

SurgiMend is substantially equivalent in function and intended use to:

Predicate Device	Manufacturer	510(k) Number
SurgiMend	TEI Biosciences	K071807
TissueMend	TEI Biosciences	K020488

Summary of Technological Characteristics and Biocompatibility

SurgiMend is substantially equivalent to other surgical meshes with respect to its design and intended use.

A rigorous biocompatibility assessment performed by an independent laboratory demonstrated the biocompatibility of SurgiMend. The tests performed included: cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, genotoxicity, intramuscular implantation, hemolysis, and pyrogenicity. The manufacturing methods for SurgiMend have also been tested by an independent laboratory to assure appropriate levels of viral inactivation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB - 4 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

TEI Biosciences, Inc.
% Kenneth James, Ph.D.
VP, Product Sciences and
Regulatory Affairs
7 Elkins Street
Boston, Massachusetts 02127

Re: K083898

Trade/Device Name: SurgiMend Collagen Matrix for Soft Tissue Reconstruction
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: January 23, 2009
Received: January 26, 2009

Dear Dr. James:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083898

Indications for Use

510(k) Number (if known): K083898

Device Name: SurgiMend Collagen Matrix for Soft Tissue Reconstruction

Indications for Use:

SurgiMend is intended for implantation to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes.

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Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K083898